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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,982	06/15/2006	Robert C. Shipman	13516-4	1560

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EXAMINER	
POHNERT, STEVEN C	
ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,982	SHIPMAN ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,50,73-75 and 78-85* is/are pending in the application.

4a) Of the above claim(s) *73-75,79-81 and 83-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,50,78 and 82* is/are rejected.

7)☒ Claim(s) *81* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/16/2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to papers filed 10/11/2007.

The amendment to the specification has overcome the objection to the specification as the hyperlinks were deleted.

The objections to claims 49 and 75 were overcome by amending the claims to recite the SEQ ID NO.

New claims 78-84 were added by amendment. It is noted that the amended claims contain two claims numbered 81, on pages 30 and 41 of the response. For clarity purposes the claim on page 41, will be addressed through the rest of this action as claim 82 and the subsequent claims will be appropriately renumbered.

Claims 49, 50, 73-75, 78-85 are pending.

Claims 79, 80, 81, 83, 84, 85 are withdrawn from consideration as directed to non-elected inventions. Specifically claims 79, 80 require 10 probes and 20 additional probes in addition to the 10 elected in response to restriction. Claim 81 requires at least 47 probes, while in response to restriction applicant elected 10 probes. Claims 83, 84, and 85 depend from claims 79, 80, and 81 and thus also require more probes than elected in response to the restriction and thus are beyond the scope of the elected invention and are thus withdrawn. Thus these claims are beyond the scope of the elected invention and thus withdrawn.

Claims 73-75 are withdrawn as directed to a non-elected invention. Claims 73-75 are drawn to a single isolated nucleic acid consisting of the sequences of parts a, b, c, or d. However, in the response to restriction of 5/16/2007 applicants elected a

combination of 10 nucleic acids and corresponding primers. Thus claims 73-75 are beyond the scope of the elected invention and thus withdrawn.

Claims 49, 50, 78 and 82 are under consideration.

This action is FINAL.

Maintained and New Grounds of Rejection Necessitated by Amendment

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 81 on page 41 has been renumbered claim 82; all subsequent claims were renumbered as well.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 49, 50, 78 and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims 49 and 50 encompass an array of two or nucleic acid "as shown in" SEQ ID NOs 12, 15, 21, 22, 23, 24, 25, 26, 35 or 44; or nucleic acid sequences prepared using amplification and primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135, or a fragment of the nucleic acids that specifically hybridize to one ABC transporter.

Further claims 78 and 82 drawn to "any" nucleic acid that specifically hybridizes nucleic acids that are broadly viewed to encode human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2. As the specification and claims do not provide any sequence information for the recited ABC transporter types this encompasses an enormous genus of nucleic acids.

When the claims are analyzed in light of the specification, the invention encompasses an enormous number of nucleotide molecules. The specification does not set forth a limiting definition of "as shown in" and "as shown in" is not an art accepted terminology. Thus "as shown in" is broadly interpreted to require a fragment of at least 2 nucleic acids up to the full length of the nucleic acid sequence. The specification teaches, " " specifically hybridizes to" it is meant that the subject nucleic acid sequence will bind, duplex or hybridize substantially to or only with a particular

nucleic acid sequence with minimum cross-hybridization with the other members of this gene family" (see page 16, 1st paragraph). As this definition allows a "minimum cross hybridization," but does not define "minimum cross hybridization" it broadly encompasses any cross hybridization. Further the claims are drawn to an amplification product defined by the use of primer pairs. Thus the claims are broadly drawn to "any" nucleic acids that can be amplified by the primers under "any" amplification conditions. This is an enormous genus of nucleic acids. Further the claims are drawn to any fragment of the nucleic acids, defined by sequence or by amplification primers. This is an enormous genus as the specification sets forth no specific definition of fragment, thus a fragment broadly encompasses a single nucleotide to any sequence that can be amplified by the primers under any conditions. This represents a genus of thousands of nucleic acids, as the each sequence claimed range from 488 to 810 nucleotides and thus a fragment can be any sequence from 2 nucleotides to the full length. The claims recitation of "specifically hybridizes to one ABC transporter genes" fails to limit the claim as it merely requires that the sequence by to one of the ABC transporter genes, but does nor preclude the fragment from hybridizing to multiple ABC transporter genes. The specification further teaches that human ABC transporters are examples of ABC transporter genes. Thus the specification teaches ABC transporter genes are from "any" species. The specification further teaches homology refers to a degree of complementary and includes partially complementary (see page 13, lines 11-15). The specification further teaches partial complementary includes less than about 30% identity (see page 13, line 27). Thus the specification teaches homology includes less

than about 30% identity. The claims read in light of the specification encompass an enormous genus of nucleic acids broadly encompassed by ABC transporter genes in "any" species. This large genus of ABC transporters broadly encompasses "any" nucleic acid that is about 30% or more identical to "any" ABC transporter gene or the recited SEQ ID NO. This genus further increases exponentially as the claims are drawn to "any" nucleic acid or primer pairs that are about 30% identical to "any" ABC transporter gene or a fragment. The claims thus encompass any primer pairs or nucleic acid or fragment that has 30% identity with any ABC transporter gene or its complement. This is an enormous genus of nucleic acids. The specification further specifically teaches they are claiming sequences that are unknown.

The specification does not define what is encompassed by the recitation of nucleic acids encoding human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2. Thus the claims broadly encompass any gene, fragment of a gene or amplification product that can broadly be interpreted to represent the recited genes. This is an enormous genus of nucleic acids.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been disclosed. The instant specification teaches SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 and primers SEQ ID NO 70, 71, 76, 77, 88-99, 116, 117, 134 and 135 sequences. The specification does not teach "any" sequences that are 30% identical to the recited SEQ

ID NO's or any fragments other than the primers taught in Table 1. The specification thus teaches 141 human sequences, which is not representative of the 100s of thousands of sequences claimed by the nucleic acid sequences, nucleic acid sequences amplified by primer pairs and their fragments.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other nucleotide sequences or positions with in a specific gene or nucleic acid), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case the specification provides only the sequences of the nucleic acids and the primers used in amplification. The specification sets forth no requirements as to the length of the fragments required, or any other functional limitations by which to determine what size of fragment is required. The claims read in light of the specification encompass any nucleic acid molecule, any nucleic amplified by the recited primer pairs or any fragment that is specifically hybridizes to "any" ABC transporter gene in "any" species or "any" nucleic acid that has 30% identity to an ABC transporter gene, SEQ ID NO or nucleic acid sequence amplified by the recited primer pairs or fragment. This is an enormous genus of nucleic acids.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The

specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acids regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

In the instant application, the provided information regarding nucleic acid ATP-binding cassette transporter fragments, homologs and genes, do not constitute an adequate written description of the broad subject matter of the claims, so one of skill in the art cannot envision the detailed chemical structure of the nucleic acids

encompassed by nucleic acids. Adequate written description requires more than a statement that nucleic acids with a particular quality are part of the invention and reference to a potential method for their identification. The nucleic acid sequence is required.

In conclusion, the limited information provided regarding an array of two or nucleic acid "as shown in" SEQ ID NOs 12, 15, 21, 22, 23, 24, 25, 26, 35 or 44; or nucleic acid sequences prepared using amplification and primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135, or a fragment of the nucleic acids that specifically hybridize to one ABC transporter. Nucleic acids encoding human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2 encompass any sequence that can broadly be interpreted to encompass the recited genes or any nucleic acid that has 30% identity, this is an enormous genus. Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Response to Arguments

The response of 10/11/2007 asserts that the amended claims satisfy the written description requirement. The response asserts on page 57, "The fragments as currently claimed are a portion of a specific sequence and have the function of being able to

specifically hybridize to one ABC transporter gene." These arguments have been thoroughly reviewed but are not considered persuasive, because the fragments can cross-hybridize to other sequences, including other ABC transporters. Further the fragments can be of any length from 1 nucleotide to the full length sequence recited, thus comprising an enormous genus of nucleic acids.

Further defining of the sequence as amplifiable by primer pairs without specific reaction conditions further represents a large genus of nucleic acids as well, as amplification conditions determine the specificity and thus the length and sequence of an amplification product. Fragments of these sequences are also claimed, the claims thus encompass a fragment of any length of any sequence that can be amplified under any conditions using the recite primers. Thus the claimed nucleic acids represent an enormous genus of thousands, if not millions of nucleic acid molecules that are represented by 141 sequences. The 141 sequences taught would not allow the artisan to envision the large genus of nucleic acids claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 49-50 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49-50 and recite, "Specifically hybridizes to one ABC transporter genes." It is unclear if the claim is drawn to a nucleic acids that specifically hybridizes to a single ABC transporter gene or nucleic acids that bind to any ABC transporter genes.

Claim 82 recites, "the probe that specifically hybridizes to the nucleic acid sequence encoding human ABC transporter B1 is the nucleic acid sequence consisting." It is unclear if the second recitation of "the nucleic acid sequence" is referring to the probe or the Human ABC transporter gene.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 49-50, and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Denefle et al (WO02/46458, published June 13, 2002).

Claim 49 is drawn to an array containing two or more of the nucleic acids of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or nucleic acid prepared by using amplification using primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135 or fragments that hybridize to one ABC transporter genes.

With regards to claim 49, Denefle teaches SEQ ID No 1-4 and 9-126. Denefle thus anticipates the claims as he teaches two or more sequences of SEQ ID NO 12, 15,

21, 22, 23, 24, 25, 26, 35, 44 or nucleic acid prepared by using amplification using primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135 or fragments that hybridize to one ABC transporter genes.

With regards to claim 50, Denefle teaches of probes attached to a solid support. The solid support of Denefle is a substrate with at least one target nucleic acid immobilized. Denefle thus anticipates claim 50.

Claim 78 requires an array with at least 10 nucleic acids that consist of SEQ ID NOs 12, 15, 21, 22, 23, 24, 25, 26, 35 or 44; or nucleic acid sequences prepared using amplification and primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135, or a fragment of the nucleic acids that specifically hybridize to nucleic acids encoding human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2. The specification teaches that specifically hybridizes allows for some cross hybridization.

With regards to claim 78, Denefle teaches SEQ ID No 1-4 and 9-126. Denefle thus anticipates the claims as he teaches 10 nucleic acid sequences on an array that are fragments of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or nucleic acid prepared by using amplification using primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and

117 or 134 and 135 and hybridize to human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2.

Response to arguments

The response asserts that the claims are limited to nucleic acids that hybridize to only one member of the ABC transporter gene family. This argument has been thoroughly reviewed but is not considered persuasive because the specification and claims do not set forth the sequences of the ABC transporter genes recited in the claims. Further the specification and response clearly teach some cross hybridization is permissible and thus, specific hybridization does not limit the claims to complete identity or complete complementarity. Finally the claims are drawn to any nucleic acid or fragment that is amplified by the recited primers under any conditions. Thus the nucleic acids of Denefle anticipate the claims.

8. Claims 49-50 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796, issue December 12, 1995).

Claim 49 is drawn to an array containing two or more of the nucleic acids of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or complements or homologs or fragments. The specification teaches homologous probes can have 30% identity. Further, the specification suggests complementary is capable of base pairing, thus the claims read on any nucleic acid or fragment with 2 bp that can base pair (see page 14, lines 23-25).

With regards to claim 49, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). The array of Brennan comprising all 10mer oligonucleotides would set forth two or nucleic acid molecules comprising a sequence that hybridizes Brennan thus anticipates the claims as he teaches two or more sequences of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or nucleic acid prepared by using amplification using primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135 or fragments that hybridize to one ABC transporter genes.

With regards to claim 50, Brennan teaches the array is a glass plate to which the oligonucleotides are immobilized (see column 7, lines 21-25). Brennan thus anticipates claim 50.

Claim 78 requires an array with at least 10 nucleic acids that consist of SEQ ID NOs 12, 15, 21, 22, 23, 24, 25, 26, 35 or 44; or nucleic acid sequences prepared using amplification and primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135, or a fragment of the nucleic acids that specifically hybridize to nucleic acids encoding human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2. The specification teaches that specifically hybridizes allows for some cross hybridization.

With regards to claim 78, Brennan teaches an array of all possible 10mer oligonucleotides (see column 9 rows 48-67). Brennan thus anticipates the claims as he teaches 10 nucleic acid sequences on an array that are fragments of SEQ ID NO 12, 15, 21, 22, 23, 24, 25, 26, 35, 44 or nucleic acid prepared by using amplification using primer pairs selected from SEQ ID NO 70 and 71, 76 and 77, 88 and 89, 90 and 91, 92 and 93, 94 and 95, 96 and 97, 98 and 99, 116 and 117 or 134 and 135 and hybridize to human ABC transporter B1, human ABC transporter B4, human ABC transporter B11, human ABC transporter C1, human ABC transporter C2, human ABC transporter C3, human ABC transporter C4, human ABC transporter C5, human ABC transporter D1, and human ABC transporter G2.

Response to arguments

The response asserts that the claims are limited to nucleic acids that hybridize to only one member of the ABC transporter gene family. This argument has been thoroughly reviewed but is not considered persuasive because the specification and claims do not set forth the sequences of the ABC transporter genes recited in the claims. Further the specification and response clearly teach some cross hybridization is permissible and thus, specific hybridization does not limit the claims to complete identity or complete complementarity. Finally the claims are drawn to any nucleic acid or fragment that is amplified by the recited primers under any conditions. Thus the nucleic acids of Brennan anticipate the claims.

Summary

No claims are allowed.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Carla Myers/
Primary Examiner, AU 1634